

Remarks

This Preliminary Amendment cancels without prejudice original claims 1 to 16 the underlying PCT Application No. PCT/EP03/00126, and adds without prejudice new claims 17 to 32. The new claims conform the claims to U.S. Patent and Trademark Office rules and do not add new matter to the application.

In accordance with 37 C.F.R. § 1.121(b)(3), the Substitute Specification (including the Abstract, but without the claims) contains no new matter. The amendments reflected in the Substitute Specification (including Abstract) are to conform the Specification and Abstract to U.S. Patent and Trademark Office rules or to correct informalities. As required by 37 C.F.R. § 1.121(b)(3)(iii) and § 1.125(b)(2), a Marked Up Version Of The Substitute Specification comparing the Specification of record and the Substitute Specification also accompanies this Preliminary Amendment. Approval and entry of the Substitute Specification (including Abstract) are respectfully requested.


The underlying PCT Application No. PCT/EP03/00126 includes an International Search Report, a copy of which is submitted herewith.

The underlying PCT Application No. PCT/EP03/00126 also includes an International Preliminary Examination Report, a copy of which is submitted herewith.

Applicant asserts that the subject matter of the present application is new, non-obvious, and useful. Prompt consideration and allowance of the application are respectfully requested.

Respectfully Submitted,
KENYON & KENYON

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By: 
Thomas C. Hughes
(Reg. No. 42,674)

One Broadway
New York, NY 10004
(212) 425-7200 (Telephone)
(212) 425-5288 (Facsimile)

2565/123

**PROCEDURE SYSTEM AND DEVICE METHOD FOR DETERMINING THE
HAEMATOCRIT HEMATOCRIT AND/OR BLOOD VOLUME**

Field of the Invention

The invention relates to a method for determining the ~~haematocrit~~ hematocrit and/or blood volume during an extracorporeal blood treatment with an extracorporeal blood circuit and an apparatus for extracorporeal blood treatment with an extracorporeal blood circuit and a device for determining the ~~haematocrit~~ hematocrit and/or blood volume.

Background

For the purpose of removing substances usually eliminated with urine and for the purpose of withdrawing fluid, ~~use is made of~~ various methods are currently employed for machine-aided blood cleaning or blood treatment in acute or chronic kidney failure. ~~Diffusive~~ A method employing diffusive substance transport ~~predominates~~ is typically employed in the case of ~~haemodialysis~~ hemodialysis (HD), whilst a method employing convective substance transport via ~~the a~~ membrane takes place in the case of ~~haemofiltration~~ (HF). ~~Haemodiafiltration~~ hemofiltration (HF). Hemodiafiltration (HDF) is a combination of ~~the~~ these two methods.

An excessively high or rapid withdrawal of fluid during ~~haemodialysis~~ hemodialysis can give rise to a possibly rapid increase in blood volume, which often leads to an acute drop in blood pressure (hypotony) in the patient.

Hypotony represents one of the main complications in the treatment of blood. ~~There are various solutions to this problem. On the one hand, Various techniques have been proposed to deal with this problem. For instance, one technique employs~~ blood pressure monitors ~~are known~~ which continuously

monitor a change in blood pressure and regulate the ultrafiltration depending on the change in blood pressure. ~~On the other hand~~ In another technique, blood volume monitors ~~are known which~~ measure the relative blood volume during the dialysis treatment and perform a regulation of the ultrafiltration depending on the relative blood volume.

German Patent No. DE-C-197 46 377 describes a device for the measurement of blood pressure, ~~which~~. This device is based on the detection of the propagation rate of the pulse waves being propagated via the arterial vessel system of the patient, ~~said these~~ pulse waves being generated by the patient's heart contractions. The device permits a continuous, non-invasive measurement of blood pressure, ~~but there is the~~. One drawback of this device is that the pulse-wave running time is dependent on the ~~haematocrit~~ hematocrit (HKT).

German Patent No. DE-A-40 24 434 describes a device for the regulation of ultrafiltration, ~~in which~~. With this device, the pressure in the extracorporeal circuit is measured in order to determine the relative blood volume. The measured pressure values are stored in chronological sequence and the change in the blood volume is ~~deduced~~ determined from the ~~the~~ change in the pressure value compared with the value at the start of the treatment. The venous return-flow or arterial suction-pressure sensor ~~can~~ may be used as a pressure sensor. ~~It is pointed out in the publication~~ The reference describes that the drop in pressure on the arterial cannula is a function of the blood flow and the viscosity of the blood as well as a function both of the diameter and length of the cannula. It is ~~further assumed~~ also described or suggested that the relationship between the blood volume and the change in pressure is a substantially linear to a good approximation: relationship.

~~The~~ One problem underlying the invention is to provide a method that permits the ~~haematocrit~~ hematocrit and/or blood volume to be determined with a

particularly high degree of accuracy, but with a relatively low technical outlay. Moreover, it is a problem of the invention to provide an apparatus for extracorporeal blood treatment with a device for determining the ~~haematocrit~~ hematocrit and/or blood volume, which has a relatively simple construction, but a high degree of accuracy.

~~The solution to this problem takes place according to the invention with the features of claims 1 and 9. Advantageous forms of embodiment are the subject-matter of the sub-claims.~~ Summary of the Invention

For reasons of safety, ~~the known~~ currently employed dialysis devices measure and monitor the arterial pressure $P_{\text{art}}(t)$ and the venous pressure $P_{\text{ven}}(t)$ in the extracorporeal blood circuit. Moreover, the rate BPR(t) of the blood pump is also measured during the blood treatment, ~~i.e. it is known as the control value.~~ The method according to the invention and the apparatus according to the invention make use of e.g., it may be employed as a control value. The present invention, according to one embodiment thereof, employs the pressure measurement that is already typically available, so that the ~~outlay on~~ cost of equipment is relatively low.

~~The basic idea of monitoring the haematocrit~~ Generally, the monitoring of the hematocrit and blood volume through the measurement of pressure is based on the following: ~~If the:~~ if a relative blood volume diminishes during ~~the~~ a blood treatment as a result of ultrafiltration, the ~~haematocrit~~ hematocrit in the blood necessarily increases, since the dialysis membrane is not permeable for the blood cells, namely erythrocytes ($7.5 \mu\text{m}$), leucocytes ($1.5 - 20 \mu\text{m}$) and thrombocytes ($2.5 \mu\text{m}$). Furthermore, the viscosity increases over-proportionately with increasing ~~haematocrit~~ hematocrit. Since the flow resistance increases in a markedly linear manner with viscosity, each increase in the ~~haematocrit~~ hematocrit caused by the reduction in blood volume signifies an increased load on the blood pump, which leads to the fall in the arterial

pressure (negative) and the increase in the venous pressure (positive), insofar as the blood pump is operated at the same rate.

It has ~~however~~ been ~~shown~~ determined that the relationship between blood volume or ~~haematocrit~~ hematocrit and pressure in the extracorporeal blood circuit is dependent not ~~only~~ merely on the blood flow, but may also be dependent on the cannula dimensions, whereby the cannula is to be regarded as the component of the extracorporeal system determining the drop in pressure. ~~The inventors recognised~~ Furthermore, it has been determined that the length of the cannula does not have any significant influence on the pressure in the extracorporeal circuit. ~~They recognised, but rather~~ that the diameter of the cannula is ~~alone decisive~~. determinative.

~~In order to increase the~~ According to one embodiment of the present invention, in order to improve accuracy, the respective relationship between ~~haematocrit~~ hematocrit or blood volume and pressure is stored for different diameters of the cannula and different values of the blood flow ~~in the case of the method and the apparatus according to the invention~~. The respective data are ~~thus already~~ thereby made readily available before, even prior to the dialysis treatment. ~~Depending on~~ Based upon the respective diameter of the cannula and the value of the blood flow, the respective relationship between ~~haematocrit~~ hematocrit or blood volume and pressure is then selected ~~and haematocrit~~. The hematocrit and/or blood volume is may then be determined taking account of the selected relationship. The data can for example be stored in the form of groups of curves, which can be described in particular by discrete measurement values.

~~The~~ Thus, an increased accuracy ~~results from the fact that account is taken not only of~~ may result because in addition to the blood flow during the treatment, ~~but also of the cannula used~~ is also considered.

In connection with hematocrit

~~When speaking of haematocrit and blood volume, both absolute values as well as relative values are to be understood~~ referred to here, which indicate a relative change in the blood volume in respect of a predetermined initial value, for example the start of the blood treatment.

An evaluation of the clinical data has ~~shown~~ demonstrated unexpectedly that in practice the arterial pressure, which is measured in the arterial blood line upstream of the blood pump, correlates with the relative blood volume much better than the venous pressure in the venous blood line. ~~This can be traced back to the fact that~~ It has been ascertained that this may result from the venous pressure is being very much more susceptible to interference than the arterial pressure. In the case of dialysis machines which make use of balancing chambers, the venous pressure sensor detects pressure fluctuations which are caused not only by the ultrafiltration, but also by switching balancing chambers. The air volume, or more precisely the level in the venous drip chamber, also has a strong influence on the characteristic of the venous pressure signal. In contrast, the arterial pressure is free from such pressure fluctuations. ~~It is true that~~ While the arterial pressure signal is influenced by the blood pumping rate, ~~but here it concerns~~ this may be an unequivocal source of interference whose influence on the arterial pressure can be compensated for.

It has been ~~shown~~ determined that the cannula diameter can be determined unequivocally by evaluating the pressure changes in the extracorporeal blood circuit. In order to determine the cannula diameter, the change in pressure resulting from a change in the blood flow is determined and the cannula diameter is ~~deduce~~ determined from the change in pressure. For this purpose, the pressures are preferably measured at at least two different values of the blood flow in each case, and the difference between the pressures is calculated. In order to determine the cannula diameter, the difference in the pressures is compared with predetermined stored value ranges representative of the individual cannula diameters. The individual value ranges can be

assigned unequivocally to the different cannula diameters. The ~~assignment~~ relationship between cannula diameter and value range can in principle be verified again by several measurements.

Furthermore, it has been ~~shown~~ determined that the relationship between ~~haematocrit~~ hematocrit or blood volume and pressure for different diameters of the cannula and different values of the blood flow can be ~~described to~~ determined with a sufficient ~~approximation~~ degree of accuracy by a non-linear function, for example a second-order polynomial. Since the blood flow correlates with the rate of the blood pump, the pumping rate, which is preset by the control of the blood treatment device, is preferably used to determine the blood flow.

When the ~~haematocrit~~ hematocrit is determined, the blood volume can be calculated. The blood volume is calculated at a specified time in the blood treatment from the product of the ~~haematocrit~~ hematocrit at a preceding time and the blood volume at a preceding time divided by the ~~haematocrit~~ hematocrit at the specified time.

The device for determining the ~~haematocrit~~ hematocrit and/or blood volume of the apparatus for extracorporeal blood treatment, according to one embodiment of the present invention, has a memory and evaluation unit, in which the respective relationships between ~~haematocrit~~ hematocrit and blood volume for the different cannula diameters and blood flows are stored. Such a memory and evaluation unit can be part of a computer control, which is may already be present in ~~the known~~ a currently employed blood treatment ~~apparatuses~~ apparatus. The measurement of the pressure preferably takes place with a pressure sensor which is may also already be present.

The determination of the cannula diameter on the basis of a pressure measurement is of ~~inherent inventive~~ particular significance. ~~The~~ This

knowledge of the influence of the cannula can be used in an advantageous way, e.g., with the a method for blood pressure measurement known from described in German Patent No. DE-C-197 46 377, in that the. The influence of the blood density on the pulse-wave running time is compensated for or corrected so that the blood pressure measurement takes place with a ~~higher~~ high degree of accuracy.

Brief Description of the Drawings

One ~~An~~ example of embodiment of an extracorporeal blood treatment apparatus with a device for determining the ~~haematocrit~~ hematocrit and/or blood volume as well as an example of embodiment of the method according to the invention are explained below in greater detail with the aid of the figures.

The figures show the following:

Fig. 1 the haematocrit is a graph that illustrates the hematocrit (HKT (%)) as a function of the arterial pressure ($P_{art}(\text{mmHg})$) for various cannulas of differing diameter and differing length, according to one embodiment of the present invention;

Fig. 2 is a graph that illustrates the hematocrit ~~Fig. 2 the haematocrit~~ (HKT (%)) as a function of the arterial pressure ($P_{art}(\text{mmHg})$) for various cannulas, according to one embodiment of the present invention;

Fig. 3 is a graph that illustrates the hematocrit ~~Fig. 3 the haematocrit~~ (HKT (%)) as a function of the arterial pressure ($P_{art}(\text{mmHg})$) for various values of the blood flow with a first cannula, according to one embodiment of the present invention;

Fig. 4 is a graph that illustrates the hematocrit ~~Fig. 4 the haematocrit~~ (HKT (%)) as a function of the arterial pressure ($P_{art}(\text{mmHg})$) for various values

of the blood flow with a second cannula, according to one embodiment of the present invention; and

Fig. 5 is a graph that illustrates the hematocrit ~~Fig. 5 the haematocrit~~ (HKT (%)) as a function of the arterial pressure (P_{art} (mmHg)) for various values of the blood flow with a third cannula, according to one embodiment of the present invention;

Fig. 6 is a diagram that illustrates generally the salient features ~~Fig. 6 an example of embodiment~~ of an extracorporeal blood treatment apparatus with a device for determining the ~~haematocrit and/or blood volume in a simplified diagrammatic representation:~~ hematocrit and/or blood volume, according to one embodiment of the present invention.

Figure 1 shows Detailed Description

Figure 1 is a graph that illustrates the relationship between the ~~haematocrit~~ hematocrit (HKT (%)) of the blood and the pressure in the arterial blood ~~line~~ line of the extracorporeal circuit with a constant blood pumping rate BPR of 250 ml/min. for seven different dialysis cannulas, which differ from one another in diameter and length. For example, the cannula with the designation V-711 has a diameter of 1.5 mm and a length of 15 mm. The other cannulas are correspondingly designated in ~~figure~~ Figure 1. It can be seen in ~~figure~~ Figure 1 that the relationship between ~~haematocrit~~ hematocrit and arterial pressure is not linear. It can, however, be described to a good approximation by a second-order polynomial. Furthermore, it can be seen that the relationship between ~~haematocrit~~ hematocrit and pressure depends markedly on the diameter of the cannulas. The influence of the length of the cannulas, on the other hand, is relatively small. ~~This~~ The influence of the length of the cannulas can therefore be neglected to a good approximation without significantly effecting accuracy. For this reason, the relationship is grouped ~~unequivocally~~ markedly according to the diameter of the cannulas, i.e. e.g., 1.5, 1.6 and 1.8

mm, respectively. Due to the marked dependence of the relationship on the diameter of cannulas, the measurement of the pressure for the determination of the ~~haematocrit~~ hematocrit or blood volume without a knowledge of the cannula diameter ~~leads~~ may lead to inaccurate results.

Figure 2 shows the relationship of ~~haematocrit~~ hematocrit and arterial pressure of a second measurement series with a blood flow rate BPR of 250 ml/min. Here too, the grouping according to the cannula diameters is distinctly marked.

Figure 3 shows the relationship between ~~haematocrit~~ hematocrit (HKT (%)) and arterial pressure (P_{art} (mmHg)) in the case of a needle with a diameter of 1.8 mm and a length of 20 mm for a large number of blood flows BPR between 100 ml/min. and 550 mm/min. Here too, the relationship is not linear. It can however again be described to a good approximation by a second-order polynomial. In a range of blood flow from 160 to 400 ml/min., the curves for different blood flows exhibit a similar gradient. Since the dependence of the blood flow, i.e. e.g., the blood pumping rate, is essentially expressed by the fact that the curves are displaced parallel to the x-axis and that the displacement is dependent on the diameter of the needle, the needle diameter can be determined unequivocally. On the assumption that the ~~haematocrit~~ hematocrit of a dialysis patient lies in the range from 30% to 40%, the diameter of the cannula can be detected without knowledge of the ~~haematocrit~~ hematocrit. The detection takes place via measurement of the pressure difference with two different blood flows, i.e. blood pumping rates, whereby typical values lie between 130 ml/min. and 310 ml/min.

Figures 4 and 5 show the groups of curves of a needle with a diameter of 1.6 mm and a length of 20 mm and respectively a needle with a diameter of 1.5 mm and length of 15 mm, respectively.

The determination of the cannula diameter with the aid of the groups of curves in ~~figures~~ Figures 3 to 5 is explained in greater detail below. Arterial pressures P_{art1} and P_{art2} are measured for this purpose at at least two predetermined blood pumping rates BPR1 and BPR2. The difference $\Delta P_{art} = \Delta P_{art1} - P_{art2}$ is then calculated, which is represented in ~~figures~~ Figures 3 to 5 as a horizontal bar. Values for ΔP_{art} that can ~~unequivocally~~ be assigned with substantial certainty to the individual cannula diameters arise for an HKT range of approximately 30 ~~to~~ 40%. These value ranges are previously determined and stored, whereby an appropriate assignment is carried out after measurement of the change in pressure.

The following table shows the pressure difference ΔP_{art} (mmHg) for the three cannulas of differing diameter (1.8, 1.6 and 1.5 mm) with a ~~haematocrit~~ hematocrit HKT of 30 and 40%. The measurement magnitudes can be grouped into the value ranges 70 ~~to~~ 90 mm Hg for a cannula diameter of 1.8 mm, 100 to 120 mm Hg for a cannula diameter of 1.6 mm and 130 to 150 mm Hg for a cannula diameter of 1.5 mm. After measurement of pressure difference ΔP_{art} , it can thus be ~~unequivocally decided what diameter~~ determined with substantial certainty the diameter of the cannula ~~has~~. It emerges that the ~~haematocrit~~ hematocrit does not have any influence on the unambiguousness of the detection of the needle diameter when it lies in the physiological range between 30 and 40%.

| HKT (%) | ΔP_{art} (mmHg) | | |
|---------|-------------------------|------------------|------------------|
| | V-501 (Ø 1.8 mm) | V-601 (Ø 1.6 mm) | V-701 (Ø 1.5 mm) |
| 30 | 72 | 102 | 130 |
| 40 | 89 | 118 | 148 |

Figure 6 ~~shows the essential~~ is a diagram that illustrates, according to one embodiment of the present invention, some of the components of an extracorporeal blood treatment apparatus together with a device for determining

the ~~haematocrit~~ hematocrit and/or blood volume in a simplified diagrammatic representation.

As a blood treatment device, the dialysis apparatus has a dialyser 1, which is divided by a semipermeable membrane 2 into a blood chamber 3 and a dialysis-fluid chamber 4. An arterial blood line 5 leads to the inlet of blood chamber 3, ~~a.~~ A peristaltic blood pump 6 ~~being is~~ is connected into ~~said the~~ the arterial blood line. A venous blood line ~~7ab 7~~ 7 leads off from blood chamber 3, ~~a.~~ A drip chamber 8 ~~being is~~ is connected into ~~said the~~ the venous blood line 7. To the ends of the arterial and venous blood line 5, 7, there are connected cannulas 5a, 7a, which are ~~jabbed~~ inserted into the patient. The arterial and venous blood line ~~are~~ may be a component of a flexible-tube line system designed to be disposable.

Fresh dialysis fluid is prepared in a dialysis-fluid source 9. A dialysis-fluid supply line 10 leads from dialysis-fluid source 9 to an inlet of dialysis-fluid chamber 4 of the dialyser, whilst a dialysis-fluid discharge line 11 leads from the outlet of the dialysis-fluid chamber to a drain 12. The dialysis apparatus also has further components, e.g. a balancing device and an ultrafiltration device etc., which however are not represented for the sake of better clarity. Moreover, the central control unit, which is a component of the dialysis apparatus, is not represented.

For safety reasons, the arterial pressure in arterial blood line 5 is monitored upstream of blood pump 6 and the venous pressure in the venous blood line is monitored downstream of drip chamber 8 in the dialysis apparatus. For this purpose, an arterial pressure sensor 13 is provided in arterial blood line 5 and a venous pressure sensor 14 is provided in venous blood line 7. The device for determining the ~~haematocrit~~ hematocrit and/or blood volume has arterial pressure sensor 13 already be available, e.g., in the dialysis apparatus ~~as well as a~~ and/or the memory and evaluation unit 15. ~~Memory~~ The memory

and evaluation unit 15 receives the pressure signal of arterial pressure sensor 13 via a data line 16. Alternatively, the memory and evaluation unit can receive the pressure signal of a venous pressure sensor 14 via a data line 17. Data line 17 is shown by a dashed line in ~~figure~~ Figure 6. Furthermore, memory and evaluation unit 15 is connected to blood pump 6 via a data line 18. A blood pump signal proportional to the blood pumping rate is transmitted via data line 18. The curve groups represented in ~~figures~~ Figures 3 to 5, which describe the relationship between ~~haematocrit~~ hematocrit and arterial pressure, are stored in the memory and evaluation unit. ~~The memory and evaluation unit operates as follows:~~

15.

According to one embodiment of the present invention, the memory and evaluation unit 15 operates in the following manner.

The cannula diameter, in which the blood pumping rate is varied, is first determined in an initial measurement during the dialysis treatment, whereby the arterial pressures P_{art1} and P_{art2} are measured at two predetermined blood pumping rates BPR of, for example, 310 and 130 mm (figure) (Figure 3). The memory and evaluation unit calculates from the measured values the amount of the pressure difference $\Delta P_A = P_{art1} - P_{art2}$, which in the present example amounts to 89 mmHg with a ~~haematocrit~~ hematocrit of 40%. In principle, however, measurements can also be carried out for other ~~haematocrit~~ hematocrit values, insofar as the ~~haematocrit~~ hematocrit lies in the physiological range of the patient and thus between 30 and 40%.

~~Apart from~~ In addition to the groups of curves, there ~~are~~ may also be stored in the memory and evaluation unit 15 the value ranges from 70 to 90, 100 to 120 and 130 to 150 mmHg characteristic of the cannula diameter, which are described above. The memory and evaluation unit performs an assignment between the measured pressure difference ΔP_{art} and the stored value ranges.

Since the measured pressure difference ΔP_{art} lies here in the value range between 70 - 90 mmHg, the memory and evaluation unit assumes that the cannula has a diameter of 1.8 mm (~~figure~~(Figure 3).

After the cannula diameter has been ascertained in the initial measurement, the memory and evaluation unit ~~carries~~ 15 may carry out a selection between the different curve groups (~~figures~~(Figures 3 ~~to~~ 5), which respectively describe the relationship of ~~haematocrit~~ hematocrit and arterial pressure for the respective needle diameter. The memory and evaluation unit 15 selects here the group of curves according to ~~figure~~ Figure 3, which are representative of the present needle diameter of 1.8 mm.

After the selection of the appropriate curve group, the memory and evaluation unit 15 determines from the appropriate curve group, with a high degree of accuracy, the appropriate ~~haematocrit~~ hematocrit in dependence on the blood pumping rate BPR(t) taking account of the diameter of the employed cannula, without the diameter of the used cannula needing to be inputted manually. If, for example, an arterial pressure of 100 mmHg is measured with the arterial pressure sensor, a ~~haematocrit~~ hematocrit of approx. 33% results with a blood pumping rate of 310 mm (~~fig.~~(Figure 3). With decreasing blood pumping rate, the ~~haematocrit~~ hematocrit increases according to the curve group.

The determination of the blood volume takes place after the ~~haematocrit~~ hematocrit has been ascertained. The blood volume at a specified time in the blood treatment RBV(t) is calculated from the ~~haematocrit~~ hematocrit HKT according to the following equation:

$$RBV(t) = \frac{HKT(t_0)RBV(t_0)}{HKT(t)}$$

whereby $RBV(t)$ is the blood volume at time t ,
 $HKT(t)$ is the ~~haematocrit~~ hematocrit at time t and $RBV(t_0)$ and $HKT(t_0)$
 are respectively the blood volume and the ~~haematocrit~~ hematocrit at an
 arbitrary time t_0 , which lies before time t .

Since $RBV(t_0) = 1$ at the start of the dialysis treatment, the memory and
 evaluation unit 15 can determine $RBV(t)$ relative to this time. On the other hand,
 the above equation can also be used for two arbitrary times t_0 and t if t_0 does not
 coincide with the start of the treatment and $RBV(t_0)$ is thus not necessarily 1. If
 $RBV(t_0)$ is not known, the memory and evaluation unit 15 can however
 determine relative changes in RBV according to the above equation compared
 with a value of $RBV(t_0)$ of 1.

Abstract

A method for determining the hematocrit and/or blood volume during an extracorporeal blood treatment with an extracorporeal blood circuit, in which blood is taken with a blood pump via an arterial cannula and an arterial flexible-tube line and blood is fed back via a venous flexible-tube line and a venous cannula. Pressure is measured in the extracorporeal blood circuit and a change in the hematocrit is determined from a change in the pressure. The respective relationship between hematocrit HKT or blood volume RBV and pressure P in the extracorporeal circuit is stored for various cannula diameters and various blood-flow values. The respective relationship for a given cannula diameter and blood flow is selected. The hematocrit and/or blood volume is determined taking account of the selected relationship.